Orthopaedic Division

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Smith+Nephew

March 16, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Written Response to Proposeded Rule to Amend Premarket Notification Regulations: 21 CFR Part 807 [Docket No. 99N-4784], *Premarket Notification: Requirement for Redacted Version Substantially Equivalent Premarket Notification*

Dear Sir or Madam:

Smith & Nephew, Inc. would like to take this opportunity to provide written comments regarding a proposed rule to amend FDA's premarket notification regulations. This proposed rule would require applicants to submit a redacted version of each premarket notification submission for which FDA has issued an order declaring the device to be substantially equivalent to a legally marketed predicate device.

Smith & Nephew, Inc. is familiar with FDA's requirements as outlined in section 513(i)(3) of the Act and the requirements of the Freedom of Information Act (FOIA), 5 U.S.C. 552, as they pertain to the release to the public of certain information contained in a 510(k). Therefore, Smith & Nephew submits the following comments in strong opposition to the proposed rule change.

- It is the practice of Smith & Nephew, Inc. to respond to a "predisclosure notification" within the time frame allotted *or* to request a time extension when necessary. There are inherent problems for industry that arise from the extremely short time frame allowed for response to a FOIA request for a redacted 510(k) (i.e. industry is given a "5 working day" time frame in which to respond). It is Smith & Nephew's opinion that there is the potential that much of industry will be penalized as the result of the actions of the few companies that do not respond within the time frame allotted pursuant to section 5 U.S.C. 552. Thus, the mandated response time frame should be reviewed and revised to provide a reasonable time frame for industry (suggest 30 day minimum).

- In the past, FOIA requests received by Smith & Nephew, Inc. for redacted 510(k)s have been accompanied by a copy of the 510(k) *including* reviewer notes and other correspondence between the submitter and FDA. With the implementation of this proposed rule, Smith & Nephew, Inc. will not have access to reviewer's notes and other correspondence likely to contain *trade secret* or *confidential commercial information*. Hence, Smith & Nephew, Inc. is unsure that such information will be properly deleted from the 510(k) records at the time FDA fulfills an FOIA request.

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- The burden of 510(k) redactment will be placed on Smith & Nephew, Inc. Historically, Smith & Nephew, Inc. receives an average of only two FOIA requests annually. The proposed rule will penalize Smith & Nephew, Inc. by requiring a redacted version of every 510(k) at submittal time.

- Claims of resource savings cited by FDA that will be redirected to expedite the 510(k) review process may not be reliable for the following reason. The hourly wage rated cited by FDA for personnel possessing the technical expertise required to properly redact a 510(k) under the current policy is not reflective of the actual resource saving anticipated by FDA. That is, personnel from the group designated to redact 510(k)s cannot be transferred into those professional/technical positions required to review 510(k)s (i.e. review personnel generally possess advanced technical degrees).

Smith & Nephew, Inc. is appreciative of the opportunity to submit written comments in strong opposition to this proposed rule change. It is vital that FDA consider industry's position on this matter before any amendment to the regulations is implemented.

Sincerely yours,

SMITH & NEPHEW, INC.

David Henley

David Henley
Clinical/Regulatory Affairs Specialist

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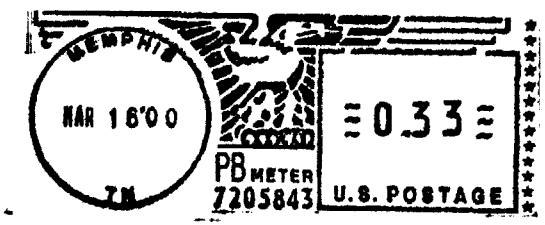

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